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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,679	02/10/2004	Assaf Friedler	18396/2282	1897

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,679

Applicant(s)

FRIEDLER ET AL.

Examiner

Agnes B. Rooke

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-29, 39, 40, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29, 44 and 45 is/are rejected.
- 7) ☒ Claim(s) 39 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This final action is in response to the Applicant's reply filed on 06/27/2005, and the amendments have been acknowledged. Claims 1-23, 30-38, 41-43, and 46-47 are cancelled. Claims 24-29, 39, 40, 44, and 45 are pending.

The application claims priority to the United Kingdom 0119557.7, filed on 08/10/2001; 0127917, filed on 11/21/2001; and 0210740.7, filed on 05/10/2002.

All Objections and Rejections not mentioned in this office action have been withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112, second paragraph

Claim 24 is rejected because it refers to a "natural binding partner," and the phrase is indefinite, since the natural binding partner can encompass an indefinite number of biological/chemical compounds and none of structures or names of the potential compounds are specified in the claim.

Applicants disagree and state that "natural binding partner" refers to a molecule that specifically binds to the native state of a given peptide in vivo in a wild-type cell or organism and that one of skill in the art would be able to recognize what is and what is not a natural binding partner on the basis of this definition.

Examiner disagrees because a "natural binding partner" is an undefined entity and therefore claim 24 is rendered indefinite.

Claim Rejections - 35 USC § 102 (b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-29, 44, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Naumovski et al., "*The p53-binding Protein 53BP2 Also Interacts with Bcl2 and Impedes Cell Cycle Progression at G2/M*," *Molecular and Cellular Biology*, (July 1996), p. 3884-3892.

Naumovski et al. teach the structure of Bcl2-binding protein ("Bbp") that specifically interacts with p53 protein in vivo, where the Bbp necessary requires for its binding to the p53 a specific ankyrin repeats and SH3 domain. See Figure 1, page 3886. Figure 3, page 3887 shows binding of Bbp protein to p53. (Claims 24, 25, and 44).

Figure 6, page 3888, shows an amino acid sequence of Bbp, which contains REDEDEIEW amino acid sequence, as part of the SH3 domain necessary for binding of the Bbp protein to p53. The REDEDEIEW amino acid sequence of Bbp protein is identical to the instant invention (Claims 27 and 45).

Therefore, the claims are anticipated by Naumovski et al. because the REDEDEIEW amino acid fragment of Bbp protein is identical to Claims 27 and 45 of the instant invention, and the amino acid fragment has the same function of binding p53 domain.

Claim 26 is included in the rejection because the structure of p53 is known and the mutations R175H, G245S, R248Q, R249S, R273H, R282W, and I195T are well known in the prior art, as pointed out by the Applicant. See specification, page 1, line 21-26, and page 2, line 1-8.

Claims 28 and 29 are included in this rejection because the stabilizing molecule is a polypeptide, and therefore it would contain, for example, a protein, polypeptide, peptide (Claim 28), and for example, an amine or amide (Claim 29), as its intrinsic characteristic.

First, Applicants state that Naumovski et al. do not teach an isolated stabilizing molecule, which binds to and stabilizes the native state of a polypeptide, but not a denatured state of the polypeptide.

Examiner disagrees, because examiner interpreted claim 24 as referring to a stabilizing molecule which binds/stabilizes the native state of a polypeptide, but not a denatured state of the polypeptide. Thus, claim 24 and 26 and all the dependent claims, are anticipated by the reference because the Bbp of Naumovski et al. will bind to a natural state of a polypeptide, such as p53, and accordingly it won't bind to a denatured state of the polypeptide, as claimed in claim 26. The reference teaches isolated stabilizing molecule that binds and stabilizes the native state of the polypeptide, where the molecule binds to a site, which at least partially overlaps a functional site of the polypeptide.

Second, Applicants state that Naumovski et al. do not teach that 53BP2/Bbp is a stabilizing molecule.

Examiner respectfully disagrees, because in the absence of the evidence to the contrary, if the 53BP2/Bbp binds to the wild-type polypeptide it stabilizes it.

Third, Applicants state that Naumovski et al. do not teach the REDEDEIEW fragment recited in claims 27 and 45.

Examiner respectfully disagrees, because the reference shows an amino acid sequence of Bbp, which contains REDEDEIEW amino acid sequence, as part of the SH3 domain necessary for binding of the Bbp protein to p53.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Kopchick et al. (U.S. 5,681,809).

Kopchick et al. teach growth hormone receptor antagonists. The GH antagonist is considered to be a stabilizing agent, which binds to the GH polypeptide functional site. See column5, line 37-43, and Abstract.

Applicants state that while the reference teaches stabilization of a GH alpha helix by mutation, the reference does not teach that it is a GH mutant that binds to and stabilizes an alpha helix of a GH molecule, as would be required for this reference to anticipate claim 24.

Examiner respectfully disagrees and stands by the rejection because claim 24 as written is anticipated by the reference because the antagonist stabilizes the receptor.

Claim Rejections - 35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24, 28, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Winnacker et al. (U.S. 6,451,541, foreign priority, May 14, 1996).

Winnacker et al. teach chaperones Hsp60 that bind to prion protein PrP^C. See column 2, line 20-34. Also, Winnacker et al. teach that prior art chemical chaperones, such as glycerol, trimethylamine N-oxide, and DMSO stabilize PrP^C and prevent its conversion to PrP^{Sc}. See column 3, line 16-24.

Applicants state that the reference cannot anticipate the claimed invention because there is no teaching that any molecule among the “chemical chaperones” described in the reference binds to and stabilizes the native state of the polypeptide, but not a denatured state of the polypeptide.

Examiner respectfully disagrees, because chemical chaperones stabilize the protein, as described above, and therefore claims 24, 28, and 29 as written are anticipated by the reference.

New Rejections and Objections

Objection to the Title

The title as currently presented does not reflect the essence of the invention.

Objection to Claims

Claims 39 and 40 are included in the rejection because they depend from rejected independent claim 24.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

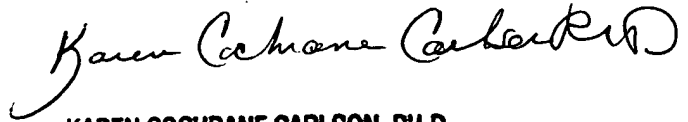
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-273-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER